U.S.S.N. 09/933,548
Art Unit: 1634
Filed: August 20, 2001
AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

Remarks

Amendment to the claims

Claims 1-37 are amended to correct multi-dependency. Claim 38 is canceled. Support is found at the claims as originally filed and at p. 66, line 9 to p. 71, line 22.

Restriction requirement

Claims 1-38 were restricted into ten groups of claims as follows:

Group I includes claims 1-4, 5-9, and 15-16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through nucleic acid analysis;

Group II includes claims 1-4, 10, 11 and 13-16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through protein analysis;

Group III includes claims 1-4, 10-13, 15 and 16, drawn to a method of determining susceptibility, diagnosing prostate cancer and predicting patient outcome through antibody analysis;

Group IV includes claims 17, 18, 21 and 22, drawn to a method of using a specific agent to determine the level of a nucleic acid;

Group V includes claims 17, 19 and 20-22, drawn to a method of using a specific agent to determine the level of a protein;

Group VI includes claim 23, drawn to a kit for detecting nucleic acids;

Group VII includes claim 23, drawn to a kit for detecting proteins;

Group VIII includes claims 24-29 and 37, drawn to a method of treating prostate cancer through nucleic acid administration;

Group IX includes claims 30-35, drawn to a nucleic acid construct; and

Group X includes claims 36 and 38, drawn to a pharmaceutical composition for treating prostate cancer.

The applicants elect group I claims with traverse. The applicants elect Pax 2 protein as the species for the prosecution of the Group II-X claims.

Claims 1-16 and 37 are drawn to a method of determining the susceptibility of, diagnosing or predicting the relative prospects of a particular outcome of prostate cancer by determining the level of Pax 2 protein or nucleic acid. Claims 17-22 are drawn to the use of an agent which is capable of use in determining the level of Pax 2 protein or nucleic acid. Claim 23 is drawn to a kit comprising an agent is capable of use in determining the level of Pax 2 protein or nucleic acid and a control sample. Claims 24-28 are drawn to a method of treating prostate cancer in a patient comprising the step of administering to the patient an agent which selectively prevents the function of Pax 2. Claim 29 is drawn to use of an agent which selectively prevents the function of Pax 2 in the manufacture of a medicament for treating prostate cancer. Claims 30-36 are dawn to a genetic construct and a pharmaceutical composition comprising a nucleic acid encoding a molecule capable of preventing the function of Pax 2 expressed in a prostate cell.

Claim 38 is cancelled.

Under PCT Rule 13, if the claims are so linked as to form a single general inventive concept, a lack of unit of invention objection is improper (See PCT Rule 13; see also MPEP § 1893.03(d)). The Examiner imposed the restriction on the basis that the claims are drawn to **nucleic acids, proteins** and **antibodies** with no consideration of the relationships between the specific nucleic acids, proteins and antibodies defined in the claims. This is clearly improper. The novel and inventive feature of the claims are **Pax 2 proteins, nucleic acids, or antibodies to the proteins** rather than proteins nucleic acids, or antibodies at large. As described at p. 5, line 25 to p. 6, line 4 and p. 57, line 25 to p. 65, line 9 (Example 1), the applicants found in the first time that Pax 2 protein is associated with prostate cancer. This finding led the applicants to make and use the compositions and methods for determining the susceptibility, diagnosing, and treating prostate cancer, which requires the determination of the level of the Pax 2 protein, nucleic acid, or an antibody to the Pax 2 protein.

Contrary to the Examiner assertion, the proteins, nucleic acids and antibodies recited or encompassed in the claims share a common technical feature as required by PCT Rule 13.2. One of ordinary skill in the art would recognize that the Pax 2 protein, nucleic acid, and the antibody to the protein are specifically interrelated. One of ordinary skill in the art would appreciate that the PAX 2 nucleic acid dictates the composition and structure of the Pax 2 protein, which, by definition, dictates the structure and composition of its antibody. Therefore, this technical feature provides unity to claims 1-37, including the alternatives Pax 2 proteins, nucleic acids, and antibodies according to PCT Rule 13.2 (see PCT Article 3(4)(iii) and 17(3)(a), PCT Rules 3.1

and 13.2; see also MPEP §1850, particularly §1850(D)). As such, the restriction requirement is clearly improper.

Withdrawal of the restriction requirement and allowance of claims 1-37, as amended are earnestly solicited.

Respectfully submitted,

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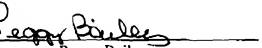
CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the enclosed Response to Restriction Requirement and all documents shown as being attached is being facsimile transmitted to the U. S. Patent and Trademark Office on the date shown below.

Date: May 22, 2003



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